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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,380	09/29/2000	Andre T. Baron	99-057	1919

7590 07/29/2003

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EXAMINER	
ANDRES, JANET L	
ART UNIT	PAPER NUMBER
1646	23

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/676,380	BARON ET AL.	
	Examin r	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communicati n appears n the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 14 May 2003 is acknowledged. Claims 1-23 are pending in this application. Claims 1-8 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

2. The rejection of claims 9-17 under 35 U.S.C. 102(a) is withdrawn in response to Applicant's declaration.

Claim Rejections Maintained

3. The rejection of claims 9-17 under 35 U.S.C. 103(a) is maintained for reasons of record in the office action of paper nos. 14 and 19.

Applicant argues that the development of the instant assay requires undue experimentation and lists factors including

1) an antibody that only recognizes denatured antigen

2) buffer conditions that do not allow the binding of the detector antibody

3) binding of the analyte to other biological molecules

4) unpredictable conformational changes

Applicant additionally argues that a direct comparison was made to the prior art in figure 7 B of Baron et al. Applicant argues that the Examiner has failed to appreciate that both assays were used to detect EGFR and that one should consequently expect 100% concordance. Applicant concludes that Applicant's assay detects a difference between healthy women and

those with cancer, unlike that sold by Oncogene Research Products, which fails to detect a difference between healthy men and women and those suffering from cancer.

Applicant's arguments have been fully considered but have not been found to be persuasive. The antibodies used by Applicant were known in the art, as was stated on p. 4 of the office action of paper no. 14. Thus no experimentation was required to develop them. Buffer conditions that "do not allow the binding of the detector antibody" are not required by the claims as written and are not specified in the claims. Binding of analyte to other molecules and unpredictable conformational changes are routine problems faced in the development of any assay and are not specific to Applicant's invention. Furthermore, there is nothing in the instant claims that requires any particular conditions to overcome such problems.

Applicant points to figure 7B of Baron et al, 1998. It is noted that Applicant subsequently argues that Baron et al. does not anticipate the claimed invention, which argument would seem to render Applicant's use of it in the instant argument inconsistent. Regardless, Baron et al. states on p. 37, column 1, that "the relationship between the current Oncogene Research Products Erb-B1 ECD-specific ELISA to the one used by Tenney, Partanen, Marley, and coworkers is ... unclear". In fact, as taught in this column, the ELISA used by Baron et al. for comparison uses different methods of detection and it is not known what antibodies were used. Thus, the comparison of Applicant's assay with that of Oncogene Research Products is not a comparison with those assays used in the art. The ability of those assays used in the art to detect a difference between men and women is therefore not addressed by figure 7b.

4. The rejection of claims 9-23 under 35 U.S.C. 112, second paragraph, is maintained for reasons of record in the office action of paper no. 19.

Applicant states that Applicant claims that their invention detects sEGFR. Applicant states that full-length EGFR is not present in body fluids and that one of skill would appreciate that distinction.

Applicant's arguments have been fully considered but have not been found to be persuasive. What Applicant claims is "an assay for determining the concentration of soluble epidermal growth factor receptor and full-length epidermal growth factor receptor" (emphasis added). See claim 9, preamble. However, what is detected is, as Applicant has pointed out and as was indicated on p. 4, paragraph 7, of the office action of paper no. 19, is "soluble epidermal growth factor receptor". See claim 9, section e). Thus, the claimed method is for detecting two things but only one thing is actually detected. The claim is therefore indefinite. Amending the claim to remove the reference to the full-length receptor would overcome this rejection. Applicant's arguments with respect to the presence of full-length EGFR in human body fluid are noted. However, claim 9 encompasses "biological sample[s]" and claim 11 limits only to "blood, serum, and plasma". Cells are found in blood and in "biological samples" generally; further, Applicant's arguments appear to indicate that the claims are drawn to methods of detecting full-length EGFR where it is not present.

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
July 17, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600